Remarks/Arguments

I. Claim Status

Prior to this amendment claims 2, 9, 10, and 11 – 15 were pending. Claims 9, and 11-15 have been cancelled without prejudice. Claim 2 has been amended to restrict the definition of R^3, R^4 and R^6 to non-heterocyclic groups. Additionally a definition for the group R^{2a} has been added. Support for this definition may be found in the specification as filed at page 20 lines 3-24 and page 21 lines 1-4.

New claims 16 and 17 have been added. Claim 16 is directed to the benzotriazole compounds described in Examples 3, 9 and 16 and pharmaceutically acceptable salts thereof. Support may be found in the specification as filed at page 43 lines 5-8; page 43 lines 1-4 and page 31 lines 9-31 through page 32 lines 1-22. Claim 17 is directed to pharmaceutical compositions comprising a compound as described in Examples 3, 9 or 16 or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier. Support may be found at page 43 lines 5-8; page 43 line 30 through page 43 lines 1-2; page 45 lines 1-4; page 31 lines 9-31 through page 32 lines 1-22 and page 34 lines 15-31 through page 35 lines 1-13.

No new matter has been added by these amendments.

II. Claim Rejections

a) 35 U.S.C. § 112 Second Paragraph

Claims 1 and 9 stand rejected under 35 U.S.C. § 112 first paragraph. The Examiner contends that the prodrugs and solvates of the compounds of the invention are not enabled. Applicants respectfully traverse this rejection. Claim 1 was cancelled in the previous amendment. Applicants are assuming the Examiner is applying this rejection to claim 2. Claim 9 has been cancelled thus rendering the rejection moot. Applicants submit that prodrugs and solvates of the compounds of the invention are enabled and have been generally described. The test for enablement is whether one reasonably skilled in the art could make and use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Applicants submit that based on the extensive teaching of the present specification a person of ordinary skill in the art can readily select any number of appropriate prodrug moieties to form prodrugs of the compounds of the invention,

or in the case of solvates, recrystallization or chromatographic solvents to form solvates of the compounds of the invention upon recrystallization or evaporation. Applicants specifically point to the specification as filed at page 37 lines 12-31 and page 38 lines 1-14 for description of various prodrugs. It is contended that one of reasonable skill would be able to choose prodrug moieties compatible with the structure of the compound of the invention based on the information in the specification and information known in the art without undue experimentation.

The Examiner in analyzing the Wands factors appears to be basing a significant part of her argument on stability and interconversion of one form into another (either prodrug or solvate) during manufacture. Applicants respectfully argue that the Examiners analysis is misplaced. In order for a prodrug to fulfill its intended function it would have to be stable to most conditions except for metabolism in the body as pointed out in the specification at page 37 lines 14-21. The prodrug moieties taught in the specification coupled with what is known in the art would enable one of reasonable skill to synthesize prodrugs that are stable except for metabolism in the body.

Solvates are crystalline or amorphous forms of compounds where solvent molecules have been trapped within the crystalline lattice structure or within the amorphous solid. Solvent molecules may in some cases be driven off upon standing, heating or under reduced pressure or a combination of heating and reduced pressure. The formation of solvates requires only some solubility of the compound in a solvent followed by recrystallization or reduction in vacuo. It is therefore contended that given the teaching of the specification coupled with what is known in the art would enable one of reasonable skill to synthesize solvates. The long or short term stability of the solvate or its stability during manufacture of the formulated drug is not relevant to the question of enablement.

Applicants respectfully request reconsideration and withdrawal of this rejection.

b) 35 U.S.C. § 112 Second Paragraph

Claims 1 and 9 stand rejected under 35 U.S.C. § 112 second paragraph. The Examiner contends that the terms "prodrug" and "solvate" in claims 1 and 9 are indefinite. Applicants respectfully traverse this rejection. Claim 1 was cancelled in the previous amendment. Applicants again assume the Examiner is applying this rejection to Claim 2. Claim 9 has been cancelled thus rendering the rejection moot. The test for indefiniteness is whether those skilled in the art would understand what is being claimed. The term "prodrug"

is a known term of art which is defined in the specification at page 37 lines 14-21. Solvates are a known term of art which is defined as a crystalline or amorphous form of a compound which contain a certain amount of a solvent. It is therefore contended that one of reasonable skill would know and understand what is being claimed and therefore the terms are not indefinite. Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

It is believed that the application is now in condition for allowance. Favorable action is earnestly solicited. If the Examiner believes a telephonic interview would expedite the prosecution of the instant case he is invited to call the applicants representative whose contact information appears below.

Respectfully submitted,

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Nicholas J. Sisti, Ph.D., J.D.
Senior Patent Agent
Reg. No. 54,453

Pfizer Inc
Patent Department
Eastern Point Road, MS8260-1611
Groton, Connecticut 06340
(860) 686-2883